

EXHIBIT 5

IN THE DISTRICT OF THE UNITED STATES OF AMERICA
FOR THE SOUTHERN DISTRICT OF ILLINOIS

IN RE DEPAKOTE;

E.R.G., a minor, by CHRISTINA RAQUEL, individually as parent and next friend of E.R.G.,

Plaintiff(s),) Case No. 15-cv-702-NJR-SCW
) Case No. 12-cv-55-NJR-SCW

ABBOTT LABORATORIES, INC.

Defendant(s).

TRIAL DAY 3

(A.M. Session)

15 BE IT REMEMBERED AND CERTIFIED that heretofore on 5/24/2017,
16 the same being one of the regular judicial days in and for the
17 United States District Court for the Southern District of
18 Illinois, **Honorable Nancy J. Rosenstengel**, United States
19 District Judge, presiding, the following proceedings were
20 recorded by mechanical stenography; transcript produced by
21 computer.

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APPEARANCES:

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FOR DEFENDANT: Dan H. Ball and Stefan Mallen of Bryan Cave - St. Louis, 211 North Broadway, One Metropolitan Square, Suite 3600, St. Louis, MO 63102; and,

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1 **MR. BALL:** Your Honor, this is getting into the area
2 that's covered by your court order from yesterday about
3 labeling issues.

4 **THE COURT:** Well, I disagree. I don't think that's
5 where the question was going.

6 **Q. (BY MR. WILLIAMS:)** You are not a labeling expert, are you?

7 **A.** No, sir.

8 **Q.** We are not going to get into labeling.

9 If you just tell somebody it's a 1 or 2 percent chance, in
10 the face of this additional information that's a 2,060 percent
11 increase does that -- does just 1 to 2 percent tell the whole
12 story, in your opinion?

13 **A.** In my opinion, it doesn't. One almost always -- when one
14 has some data that suggests that something is either associated
15 with or causes a problem you say how big that increase is, what
16 the statistical significance of that is, and then if you can --
17 and sometimes you can't do this -- you then try to relate it to
18 what does that mean in terms of 100 women? And so you get this
19 first information that doesn't have in it the rate in 100
20 women, you sort of have to guess at that. It is an educated
21 guess, and we were willing to do that.

22 And so the way that came was we knew in Atlanta that spina
23 bifida was about a 1 in 1,000 event at that time, and so if you
24 did 20 times that, that would be 2 percent. And so that's how
25 you make it.

1 So, for me, there are two reasons for having the relative
2 risk or this increased risk of the odds ratio is that -- first
3 of all, it's what you actually measure in case control studies.
4 That's what everybody does. And then you have to then make a
5 bit of a guess to temporize. And often when we would make a
6 statement from the CDC, based on seeing that there was an
7 increased risk, we would also try to balance that out with
8 saying what the absolute risk is, what it would be for a
9 hundred women.

10 And because often, I think, when a woman or anyone would
11 hear a 20-fold risk, you would think it's certain that my kid
12 is going to have this. And if you were taking a drug that was
13 important, you might suddenly stop it or -- which would not be
14 what we would -- we would want to minimize that. We would want
15 people to see their doctor and be able to do things, so we
16 would try to temporize. So putting in the 1 to 2 percent was a
17 way to temporize and so women could get to there.

18 So, in my view, the relative risk is always the most
19 threatening, the most obvious way to say how big the risk is.
20 And the other is important to have. There are really two sides
21 of the same coin when you have enough information to do it.

22 **Q.** Does one have to know the background risk, though, to
23 calculate this 2,060 percent?

24 **A.** Say that again, please.

25 **Q.** Does one have to know the background rate of spina bifida

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22 **Q.** Does one have to know the background risk, though, to
23 calculate this 2,060 percent?

24 **A.** Say that again, please.

25 **Q.** Does one have to know the background rate of spina bifida

1 in order to calculate this 2,060 percent increased risk?

2 **A.** So what I think I hear you saying is that if you knew from
3 a study or if you knew and you read that the risk was
4 1 percent, what would you need to do to figure out how big that
5 increase was?

6 And, yes, you would have to know that. And then you would
7 have to do the math to figure it out, which is, in some ways,
8 simply arithmetic, but it's not something that I think most --
9 most physicians would walk around knowing what the background
10 premise of spina bifida is. So as a epidemiologist, we knew
11 that. We looked it up in our studies and we calculated it, but
12 I think it would be a pretty rare physician who would be able
13 to take the 1 percent and say, Ah, that's a 20-fold increase.
14 I think, you know, one in a million, but not very many.

15 **Q.** So the -- and the 20.6, that's the same as the 2,060
16 percent increase, right?

17 **A.** Yes.

18 **Q.** And as an epidemiologist and a physician, is that an
19 important number that you think for physicians that they should
20 know?

21 **A.** Yes.

22 **Q.** Okay. Do you know of any other cause of spina bifida,
23 known cause, other than valproic acid?

24 **A.** Yes.

25 **Q.** What is that?